

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Maria PALASIS et al.
SERIAL NO. : (Continuation of 09/457,254)
FILED : Herewith
FOR : LATERAL NEEDLE INJECTION APPARATUS AND
METHOD
GROUP ART UNIT : 3763 (Anticipated)
EXAMINER : M. Mendez (Anticipated)
ASSISTANT COMMISSIONER
FOR PATENTS
Washington, D.C. 20231

PRELIMINARY AMENDMENT

SIR:

Prior to examination of the above-identified application on the merits, please amend the application as follows:

IN THE SPECIFICATION

Please amend the specification by inserting the following sentence under the Title:

-- This application is a continuation application of application Serial No. 09/457,254 filed December 8, 1999, which claims the benefit of provisional application Serial No. 60/133,122, filed May 7 1999, the entire disclosures of which are incorporated by reference.--

Please amend the specification at page 1, second paragraph, beginning at line 6 as follows:

-- This application is related to co-pending Patent Application Serial No. 09/457,453, filed on even date herewith, entitled INJECTION ARRAY APPARATUS AND METHOD; co-pending Patent Application Serial No. 09/457,193, filed on even date herewith, entitled LATERAL NEEDLE-LESS INJECTION APPARATUS AND METHOD; and co-pending

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Patent Application Serial No. 09/456,456, filed on even date herewith, entitled NEEDLE-LESS INJECTION APPARATUS AND METHOD. --

In the Claims

Please cancel claims 1-27 in their entirety without prejudice or disclaimer and add the following new claims:

-- 28. (New) A catheter comprising:

a shaft having a proximal end and a distal end, the distal end of the shaft including a primary penetrating member and at least one secondary penetrating member, wherein the primary penetrating member is adapted to penetrate tissue in a first direction, and wherein the at least one secondary penetrating member is retractable to a position within the primary penetrating member and penetrates the tissue in a second direction different from the first direction when extended from the primary penetrating member.

29. (New) The catheter of claim 28, wherein the tissue is selected from the group consisting of tumors, heart, lung, brain, liver, kidney, bladder, urethra, ureters, eye, intestines, stomach, pancreas, ovary, prostate, skeletal muscle, smooth muscle, breast, cartilage and bone.

30. (New) The catheter of claim 28, wherein the at least one secondary penetrating member comprises microneedles.

31. (New) The catheter of claim 28, wherein the second direction is generally perpendicular to the first direction.

32. (New) The catheter of claim 28, wherein the second direction is at an angle of about 5 to about 90 degrees relative to the first direction.

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33. (New) A catheter system comprising:

a pressurized fluid source including fluid therein; and

a catheter having a proximal end and a distal end, wherein the proximal end of the catheter is connected to the pressurized fluid source, wherein the distal end of the catheter includes a primary penetrating member and at least one secondary penetrating members, wherein the primary penetrating member is adapted to penetrate tissue in a first direction, and wherein each of the at least one secondary penetrating members is retractable to a first position within the primary penetrating member and a second position extended from the primary penetrating member, with each of the at least one secondary penetrating members having a lumen in fluid communication with the pressurized fluid source such that fluid may be delivered to the tissue via the secondary penetrating members.

34. (New) The catheter system of claim 33, wherein the secondary penetrating members penetrate the tissue in a second direction different from the first direction when extended from the primary penetrating member.

35. (New) The catheter system of claim 33, wherein the second direction is generally perpendicular to the first direction.

36. (New) The catheter system of claim 33, wherein the second direction is at an angle of about 5 to about 90 degrees relative to the first direction.

37. (New) The catheter system of claim 33, wherein the tissue is selected from the group consisting of tumors, heart, lung, brain, liver, kidney, bladder, urethra, ureters, eye, intestines, stomach, pancreas, ovary, prostate, skeletal muscle, smooth muscle, breast, cartilage and bone.

38. (New) The catheter system of claim 33, wherein the fluid comprises at least one therapeutic agent.

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39. (New) The catheter system of claim 33, wherein the at least one secondary penetrating member comprises microneedles.

40. (New) A method of delivering fluid to an injection site of tissue of a patient comprising:

providing a catheter comprising a shaft having a proximal end and a distal end, the distal end of the catheter including a primary penetrating member and at least one secondary penetrating members, wherein the primary penetrating member is adapted to penetrate tissue in a first direction, and wherein each of the at least one secondary penetrating members is retractable within the primary penetrating member and penetrates the tissue in a second direction different from the first direction when extended from the primary penetrating member;

inserting the catheter into the patient;

navigating the catheter until the distal end of the catheter is positioned adjacent the injection site;

actuating the primary penetrating member with the at least one secondary penetrating member retracted within the primary penetrating member such that the primary penetrating member penetrates the tissue at the injection site in a first direction;

actuating the at least one secondary penetrating member by extending the at least one secondary penetrating member from the primary penetrating member such that the at least one secondary penetrating member penetrates the tissue in a second direction different from the first direction; and

injecting the fluid into the tissue via the at least one secondary penetrating member.

41. (New) The method of claim 40, wherein the tissue is selected from the group consisting of tumors, heart, lung, brain, liver, kidney, bladder, urethra, ureters, eye, intestines, stomach, pancreas, ovary, prostate, skeletal muscle, smooth muscle, breast, cartilage and bone.

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42. (New) The method of claim 40, wherein the fluid comprises at least one therapeutic agent.

43. (New) The method of claim 40, wherein the second direction is at an angle of about 5 to about 90 degrees relative to the first direction.

44. (New) The method of claim 40, wherein the tissue is selected from the group consisting of tumors, heart, lung, brain, liver, kidney, bladder, urethra, ureters, eye, intestines, stomach, pancreas, ovary, prostate, skeletal muscle, smooth muscle, breast, cartilage and bone.

45. (New) The method of claim 40, wherein the at least one secondary penetrating member comprises microneedles.--

REMARKS

Entry of the amendments above and favorable consideration of this application are respectfully requested in view of the comments below.

The specification is amended herein to include related U.S. application data. The original claims are canceled herein and replaced with new claims 28 through 45. Accordingly, claims 28 - 45 are presented for examination on the merits. The new claims are believed to be supported by the specification. Favorable consideration of these claims, is respectfully requested.

Applicants request that the preceding specification and claim amendments be made of record and fully considered before the first Office Action on the merits. The amendments to the specification and claims are shown in the "Version with Markings to Show Changes Made," which is attached hereto.

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The Examiner is invited to contact the undersigned at (202) 220-4200 to discuss any matter concerning this application. The Office is authorized to charge any fees or credit any overpayment under 37 C.F.R. §§1.16 or 1.17 to Deposit Account No. 11-0600.

Respectfully submitted,
KENYON & KENYON

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Version with Markings to Show Changes Made

In the Specification:

The paragraph beginning at page 1, line 6 is amended herein as follows:

-- This application is related to co-pending Patent Application Serial No. []
09/457,453, filed on even date herewith, entitled INJECTION ARRAY APPARATUS AND
METHOD; co-pending Patent Application Serial No. [] 09/457,193, filed on even
date herewith, entitled LATERAL NEEDLE-LESS INJECTION APPARATUS AND
METHOD; and co-pending Patent Application Serial No. [] 09/456,456, filed on
even date herewith, entitled NEEDLE-LESS INJECTION APPARATUS AND METHOD. --

In the Claims:

Claims 1-27 are canceled herein.